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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/790,561 | 03/01/2004 | James F. Zucherman | SFMT-01095US0 | 9704 |
| 23910 | 7590 | 04/04/2007 | EXAMINER | |
| FLIESLER MEYER LLP 650 CALIFORNIA STREET 14TH FLOOR SAN FRANCISCO, CA 94108 | | | CUMBERLEDGE, JERRY L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | | DELIVERY MODE | |
| 3 MONTHS | 04/04/2007 | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/790,561 | ZUCHERMAN ET AL. |
| | Examiner | Art Unit |
| | Jerry Cumberledge | 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,7,8,24,25,30,31 and 33-47 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1,2,7,8,24,25,30,31 and 33-47 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 March 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08). Paper No(s)/Mail Date <u>1/12/07 6/24/05 5/02/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION***Specification***

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24, 25 and 35 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 24, lines 7-9, applicant positively recites part of a human, i.e. "...where the first fastener surrounds the first spinous

process...where the second fastener surrounds the second spinous process...".

Thus claims 24, 25 and 35 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 8, 24, 25, 30, 31 and 33-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Tofflemire (US Pat. 2,502,902).

Tofflemire discloses an implant adapted to be inserted between adjacent first and second spinous processes comprising: a first end (Fig. 8, left end of ref. M) that defines a first saddle (Fig. 8, ref. 23, left); a second end (Fig. 8, right end of ref. M) that defines a second saddle (Fig. 8, ref. 23, right); a first tether (Fig. 8, left cable) associated with the first saddle; a second tether (Fig. 8, right cable) associated with the second saddle; the first tether adapted to retain the first spinous process relative to the first saddle; the second tether adapted to retain

the second spinous process relative to the second saddle wherein the implant comprises a unitary body (Fig. 8, ref. M) that is located between the first and second ends, and wherein the unitary body defines the first saddle at the first end (Fig. 8) that is adapted to be in direct contact with the first spinous process and the second saddle at the second end (Fig. 8) that is adapted to be in direct contact with the second spinous process; and wherein the first saddle is defined between a first leg (as best seen in Fig. 14, ref. 23, left) and a first side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, left) and the second saddle is defined between a second leg (Fig. 14, ref. 23, right) and a second side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, right), with the first tether associated with the first leg and the first side of the body and the second tether associated with the second leg and the second side of the body (Fig. 8). The first tether is separate from the second tether (Fig. 8).

Tofflemire discloses an implant adapted to be inserted between adjacent first and second spinous processes comprising: a first end (Fig. 8, left end of ref. M) that defines a first saddle (Fig. 8, ref. 23, left); a second end (Fig. 8, right end of ref. M) that defines a second saddle (Fig. 8, ref. 23, right); a first fastener (Fig. 8, left cable) associated with the first saddle, which first fastener is adapted to surround the first spinous process; a second fastener (Fig. 8, right cable) associated with the second saddle, which second fastener is adapted to surround the second spinous process; the first fastener adapted to retain the first spinous process relative to the first saddle; the second fastener adapted to retain the second spinous process relative to the second saddle wherein the implant

comprises a unitary body (Fig. 8, ref. M) that is located between the first and second ends, and wherein the unitary body defines the first saddle at the first end that is adapted to be in direct contact with the first spinous process and the second saddle at the second end that is adapted to be in direct contact with the second spinous process; and wherein the first saddle is defined between a first leg (as best seen in Fig. 14, ref. 23, left) and a first side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, left) and the second saddle (Fig. 14, ref. 23, right) is defined between a second leg (Fig. 14, ref. 23, right) and a second side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, right) with the first tether associated with the first leg and the first side of the body and the second tether associated with the second leg and the second side of the body (Fig. 8). The first fastener is separate from the second fastener (Fig. 8).

Tofflemire discloses an interspinous process implant adapted to be inserted between a first and a second spinous process comprising: a unitary body (Fig. 8, ref. M) having first end (Fig. 8, left end of ref. M) defining a first saddle (Fig. 8, ref. 23, left), a second end (Fig. 8, right end of ref. M) defining a second saddle (Fig. 8, ref. 23, right), where the first and second saddles are adapted to directly engage first and second spinous processes, respectively; a first fastener (Fig. 8, left cable) secured to the first saddle; and a second fastener (Fig. 8, right cable) secured to the second saddle. At least one of the first or second fasteners is a tether (Fig. 8, cables).

Tofflemire discloses in an interspinous process implant, the improvement

comprising a unitary central body (Fig. 8, ref. 23) with first (Fig. 8, ref. 23, left) and second saddles (Fig. 8, ref. 23, right) adapted to receive adjacent spinous processes, the interspinous process implant having at least one tether (Fig. 8, left cable) secured to at least one saddle (Fig. 8) in order to retain the interspinous process implant between the interspinous processes.

Tofflemire discloses in an interspinous process implant the improvement comprising a body (Fig. 8, ref. M) with first (Fig. 8, ref. 23, left) and second (Fig. 8, ref. 23, right) saddles adapted to receive adjacent spinous processes, the interspinous process implant having a first tether (Fig. 8, left cable) secured relative to one saddle (Fig. 8) and a second tether (Fig. 8, right cable) that is secured relative to the other saddle (Fig. 8) in order to retain the interspinous process implant between the interspinous processes. The unitary body is configured to distract the first and second spinous processes. The unitary body is configured to distract the first and second spinous processes. The unitary body is configured to distract the first and second spinous processes. The implant is configured to distract the adjacent spinous processes. The implant is configured to distract the adjacent spinous processes. The first tether is securable to the first leg and to the first side of the body and the second tether is securable to the second leg and to the second side of the body. The first tether is securable through a first bore (Fig. 14, the bore in the lower portion of the "J" shape of the first leg) in the first leg and the second tether is securable through a second bore (Fig. 14, the bore in the lower portion of the "J" shape of the second leg) in the second leg. The first tether is securable through a first bore (Fig. 14, the bore in

the lower portion of the "J" shape of the first leg) in the first leg and is securable to the first side of the body and the second tether is securable through a second bore (Fig. 14, the bore in the lower portion of the "J" shape of the second leg) in the second leg and is securable to the second side of the body. The first fastener is securable to the first leg and to the first side of the body and the second fastener is securable to the second leg and the second side of the body. The first fastener is securable through a first bore (Fig. 14, the bore in the lower portion of the "J" shape of the first leg) in the first leg and the second fastener is securable through a second bore (Fig. 14, the bore in the lower portion of the "J" shape of the second leg) in the second leg. The first fastener is securable through a first bore (Fig. 14, the bore in the lower portion of the "J" shape of the first leg) in the first leg and is securable to the first side of the body and the second fastener is securable through a second bore (Fig. 14, the bore in the lower portion of the "J" shape of the second leg) in the second leg and is securable to the second side of the body.

Tofflemire discloses an implant adapted to be inserted between adjacent first and second spinous processes comprising: a first end (Fig. 8, left end of ref. M) that defines a first saddle (Fig. 8, ref. 23, left); a second end (Fig. 8, right end of ref. M) that defines a second saddle (Fig. 8, ref. 23, right); a first tether (Fig. 8, left cable) associated with the first saddle; a second tether (Fig. 8, right cable) associated with the second saddle; the first tether adapted to retain the first spinous process relative to the first saddle; the second tether adapted to retain the second spinous process relative to the second saddle wherein the implant

comprises a unitary body (Fig. 8, ref. M) that is located between the fast and second ends, and wherein the unitary body defines the first saddle at the first end (Fig. 8) that is adapted to be in direct contact with the first spinous process and the second saddle at the second end (Fig. 8) that is adapted to be in direct contact with the second spinous process; and wherein the first saddle is associated with a first leg (as best seen in Fig. 14, ref. 23, left) and a first side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, left) and the second saddle is associated with a second leg (Fig. 14, ref. 23, right) and a second side of the body (Fig. 14, ref. 23, right) with the first tether associated with the first leg and the first side of the body and the second tether associated with the second leg and the second side of the body (Fig. 8). The first tether is securable to the first leg and to the first side of the body and the second tether is securable to the second leg and to the second side of the body.

Tofflemire discloses an implant adapted to be inserted between adjacent first and second spinous processes comprising: a first end (Fig. 8, left end of ref. M) that defines a first saddle (Fig. 8, ref. 23, left); a second end (Fig. 8, right end of ref. M) that defines a second saddle (Fig. 8, ref. 23, right); a first tether (Fig. 8, left cable) associated with the first saddle; a second tether (Fig. 8, right cable) associated with the second saddle; the first tether adapted to retain the first spinous process relative to the first saddle; the second tether adapted to retain the second spinous process relative to the second saddle wherein the implant comprises a body (Fig. 8, ref. M) that is located between the first and second ends, and wherein the body defines the first saddle at the first end that is

adapted to be associated with the first spinous process (Fig. 8) and the second saddle at the second end that is adapted to be associated with the second spinous process (Fig. 8); and wherein the first saddle is associated with a first leg (as best seen in Fig. 14, ref. 23, left) and a first side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, left) and the second saddle is associated with a second leg (Fig. 14, ref. 23, right) and a second side of the body (Fig. 14, the side of ref. M immediately adjacent to ref. 23, right) with the first tether associated with the first leg and the first side of the body and the second tether associated with the second leg and the second side of the body (Fig. 8). The first tether is securable to the first leg and to the first side of the body and the second tether is securable to the second leg and to the second side of the body.

With regards to statements of intended use and other functional statements (e.g. ...adapted to retain the first spinous process relative to the first saddle..., ... adapted to be in direct contact with the first spinous process..., ... the first and second saddles are adapted to directly engage first and second spinous processes, respectively...), they do not impose any structural limitations on the claims distinguishable over the device of Tofflemire, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218

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USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

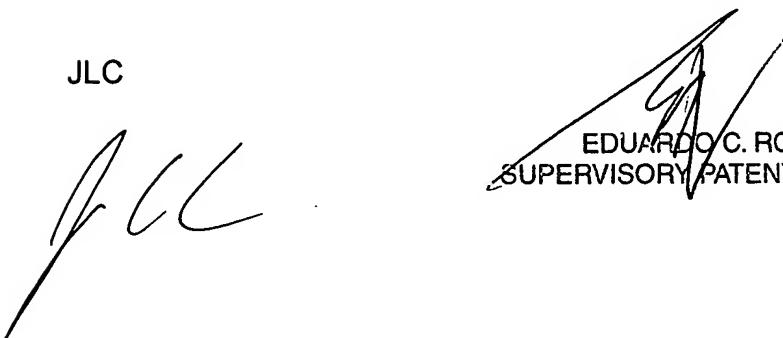
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER